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LEXICON GENETICS INCORPORATED
8800 TECHNOLOGY FOREST PLACE
THE WOODLANDS, TX 77381-1160

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FRONDA, CHRISTIAN L	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 20031128

Application Number: 09/755,016
Filing Date: January 05, 2001
Appellant(s): WALKE ET AL.

David W. Hibler
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 09/09/2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1, 2, and 5-10 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Attwood et al. Which craft is best in bioinformatics? Comput. Chem. 2001, Vol. 25(4), pp.329-339.

Ponting, C.P. Issues in predicting protein function from sequence. Brief. Bioinform. March 2001, Vol. 2(1), pp. 19-29.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

35 U.S.C. § 101

Claims 1, 2, and 5-10 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. This rejection is set forth in prior Office Action of 09/09/2002, and supplemented in the Office Action of 03/06/2003 and the Advisory Action dated 07/08/2003.

The instant specification discloses the nucleotide sequence of SEQ ID NO: 3 and the deduced amino acid sequence of SEQ ID NO: 4. The specification states that the protein consisting of SEQ ID NO: 4 is a "novel human protein" (NHP) sharing structural similarity with "trypsin-like serine proteases" (see page 15, line 30) which is a generic asserted utility. The specification does not specifically disclose the function/activity of the protein consisting of SEQ ID NO: 4 or its relationship to any disease. The specification does not show any enzyme assays that demonstrate that the protein consisting of SEQ ID NO: 4 has any protease activity. There is no disclosed or "real

world" utility associated with the nucleic acid of SEQ ID NO: 3 or the protein of SEQ ID NO: 4.

It appears that the main utility of the nucleic acids and protein is to carry out further research to identify the biological function and possible diseases associated with the nucleic acids and protein. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific and substantial asserted utility or a well established utility.

35 U.S.C. § 112, 1st Paragraph - Enablement

Claims 1, 2, and 5-10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

35 U.S.C. § 112, 1st Paragraph - Written Description

Claim 1 and 7-10 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is set

forth in prior Office Action of 10/26/2001 and Office Action of 09/09/2002, and supplemented in the Office Action of 03/06/2003 and the Advisory Action dated 07/08/2003.

Claim 1 is directed to all possible polynucleotides comprising at least 60 contiguous nucleotide of SEQ ID NO: 3 and of any biological function. The specification, however, only provides the following representative species encompassed by these claims: a polynucleotide consisting of a nucleotide sequence of SEQ ID NO: 3. There is no disclosure of any particular structure to function/activity relationship in the disclosed species. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties other than the polynucleotide comprises at least 60 contiguous nucleotide of SEQ ID NO: 3 for which no predictability of structure is apparent.

The specification does not provide a written description of the nucleotide sequence that is 5' or 3' of 60 contiguous nucleotides of SEQ ID NO: 3 or the biological functions of the polynucleotide encompassed by the claim. Given this lack of additional representative species as encompassed by the claims, Appellants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Appellants were in possession of the claimed invention. Claims 7-10 which depend from claim 1 are also rejected because they do not correct the defect of claim 1.

(11) Response to Argument

Appellants argue on pages 5-10 of the Brief that the present nucleic acids have utility in forensic analysis by distinguishing individuals in a human population from one another based on the presence or absence of three coding single nucleotide polymorphisms cited in the specification (p. 15, lines 22-29) and that such polymorphisms are the basis for forensic analysis which is asserted as a "real world" utility".

However, Appellants mischaracterize the specification since the specification describes potential polymorphisms but not actual polymorphisms which have been demonstrated. The specification states on page 15, lines 22-30:

> "...the described NHP sequences **can** contain a variety of polymorphisms such as at nucleotide 28 of SEQ ID NO:3 and nucleotide 55 of SEQ ID NO:3 which both can be a C or a T and **can** give rise to silent mutation at corresponding amino acid position 10 of SEQ ID NO:4 or a tyr or his at amino acid position 19 of SEQ ID NO:4. The described NHP sequences can also contain G-A polymorphisms at nucleotide 379 of SEQ ID NO:3 and nucleotide position 199 of SEQ ID NO:5 which **can** give rise to a corresponding ala or thr at amino acid position 127 of SEQ ID NO:4, or residue 67 of SEQ ID NO:6. The described NHPS share similarity with trypsin-like proteases, plasminogens, and acrosins." (emphasis added)

While forensic analysis can be useful for determining the presence or absence of polymorphisms which have been demonstrated to exist, it is uncertain how the instant invention provides a beneficial use in forensic analysis when the instant specification only describes **potential** polymorphisms but not actual polymorphisms. It is uncertain how these potential polymorphisms cited in the instant specification can be useful markers when the specification does not disclose that the claimed polynucleotides are specific markers for specific individual(s) of the human population. Furthermore, the specification does not teach any meaningful interpretation of data collected from such forensic analysis for determining the presence or absence of the potential polymorphisms cited in the specification on page 15, lines 22-30. Therefore, the asserted utility is not specific and not substantial.

Appellants argue beginning on page 10, 2nd full paragraph, that spurious publications have been put forth by the PTO which cast doubt about the usefulness of bioinformatic predictions in order to deny utility of the claimed polynucleotide. Furthermore, beginning on page 11, 1st full paragraph, Appellants argue that the sequence homology alignments of Exhibit A and Exhibit B show that the claimed sequence has 100% identity at the protein level "over an extended region of the claimed sequence" to polynucleotide references cited as GenBank accession number XM-171629 and GenBank accession number XM-208689 and that one of skill in the art would believe that the claimed polynucleotide encodes a serine protease.

Appellants arguments have been fully considered but are not found to be persuasive for several reasons. The cited references of Attwood et al. and Ponting are not spurious publications because the references provide rational and scientific explanations of the pitfalls in predicting or assigning any biological function base solely on a polynucleotide sequence or a deduced amino acid sequence. Attwood et al. teach "...we do not fully understand the rules of protein folding, so we cannot predict protein structure; and we cannot invariably diagnose protein function, given knowledge only of its sequence or structure in isolation".

The specification does not explicitly state that homology to a reference polynucleotide known in the prior art is a disclosure that the claimed polynucleotide has the properties and biological function of the reference polynucleotide relied upon. No further information is provide by the specification regarding the specific activity and function of the claimed polynucleotide other than the encoded protein is a "novel human protein" (NHP) sharing structural similarity with "trypsin-like serine proteases" (see page 15, line 30).

Appellants mischaracterize the cited GenBank references. A careful review of each of the polynucleotide references of GenBank accession number XM-171629 and GenBank accession number XM-208689 indicates that the annotations recite that the product encoded by the polynucleotide are "**similar** to cortical granule serine protease 1" (emphasis added). The polynucleotide references do not state that encoded product is a serine protease activity nor do the references show that the product has been demonstrated to have any serine protease activity.

Accordingly, one of skill in the art cannot conclude that the claimed invention is a serine protease as appellants have asserted since homology to polynucleotide references GenBank accession number XM-171629 and GenBank accession number XM-208689 is not a disclosure that the claimed polynucleotide encodes a serine protease, the polynucleotide references relied on simply state that the reference polynucleotide encodes a product that is assigned as "**similar** to cortical granule serine protease 1" (emphasis added) and that Attwood et al. teach that protein function cannot be determined "given knowledge only of its sequence or structure in isolation".

Appellants argue beginning on page 12, 1st full paragraph, that the claimed polynucleotides have utility as described in the instant specification in assessing gene expression patterns using high-throughput DNA chips. Furthermore, beginning of page 14, 1st full paragraph, Appellants argue that the claimed polynucleotide as described in the instant specification has a specific utility in "determining the genomic structure" of protein coding regions on the human chromosome.

This is not found to be persuasive because any new polynucleotide can be used in applications for determining the expression pattern of the new polynucleotide, and thus this asserted utility is not specific. While the claimed invention can be used in gene expression monitoring experimentations, the specification does not teach any meaningful interpretation of data collected from such experimentations, and thus this asserted utility is not substantial. Furthermore, any new polynucleotide can be used in further experimentation to determine the genomic structures of yet to be discovered

protein coding regions on the human chromosome, and thus this asserted utility is not specific.

The instant application has failed to provide either a specific and substantial asserted utility or a well established utility. The proposed uses of the claimed invention are starting points for further experimentation and investigation into specific beneficial uses of the claimed polynucleotides.

Beginning on page 17, part B., Appellants argue that claims 1, 2, and 5-10 have been shown to have a "specific, substantial, and credible utility" for the reasons stated in Section VIII(A) above and that the rejection under 35 U.S.C. § 112, 1st paragraph, cannot stand. This not found to be persuasive since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Until a specific and substantial utility can be determined for the claimed polynucleotide and polypeptide encoded, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there is no immediately apparent or "real world" utility as of the filing date of the instant invention.

Appellants argue on pages 18-19 of the Brief that in order to comply with 35 U.S.C. § 112, first paragraph, Appellants need only to " convey the invention with reasonable clarity to the skilled artisan". Appellants argue on pages 19-20 that the

nucleic acids of the invention are distinguished from other materials on the basis of structural features, specifically, the nucleotide sequence itself. Appellants further argue that polynucleotides comprising at least 60 contiguous of SEQ ID NO: 3 are within the genus of the instant claims and while polynucleotides which do not comprise at least 60 contiguous of SEQ ID NO: 3 are outside the genus.

Appellants conclude that defining the claimed genus by structural terms, i.e. nucleotide sequence, is all that is required to meet the written description requirement 35 U.S.C. § 112, first paragraph. Appellants summarize several cases on pages 18-20 of the Brief to support their arguments.

Appellants arguments have been fully considered but are not found to be persuasive for several reasons. A review of the language of claim 1 indicates that the claim is drawn to a genus of polynucleotides that minimally contains at least 60 contiguous nucleotides of SEQ ID NO: 3 and encompasses a wide breadth of polynucleotides with biological functions that have yet to be discovered such as encoding proteins and enzymes. A description of the genus of polynucleotides that minimally contain at least 60 contiguous nucleotides of SEQ ID NO: 3 may be achieved by a recitation of a representative number of polynucleotides defined by nucleotide sequence and falling within the scope of the genus. Alternatively, description of the genus of polynucleotides may be achieved by recitation of structural features that are common to the members of the genus.

However, the instant application only discloses only one species encompassed by the claim: a polynucleotide consisting of a nucleotide sequence of SEQ ID NO: 3.

There is no disclosure of any particular structure to function or activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties other than comprising at least 60 contiguous nucleotide of SEQ ID NO: 3 for which no predictability of structure is apparent.

The specification does not provide a written description of the nucleotide sequence that is 5' or 3' of the 60 contiguous nucleotides of SEQ ID NO: 3 nor does the specification provide a written description of all the polynucleotides and their biological functions which have yet to be discovered as encompassed by the claimed genus where the members of the claimed genus minimally contain at least 60 contiguous nucleotides of SEQ ID NO: 3.

Given the lack of additional representative species as encompassed by the claimed genus, the wide breadth of polynucleotides with biological functions that have yet to be discovered as encompassed by the claimed genus, and the lack of any particular structure to function or activity relationship in the single disclosed species of nucleic acid consisting of a nucleotide sequence of SEQ ID NO: 3; one of skill in the art would not recognize from the disclosure that Appellants were in possession of the genus of polynucleotides comprising at least 60 contiguous nucleotides of SEQ ID NO: 3. Claims 7-10 which depend from claim 1 are also rejected because they do not correct the defect of claim 1. Hence, claims 1 and 7-10 do not meet the written description requirement of 35 U.S.C. § 112, first paragraph.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Christian L. Fronda
November 29, 2003

Conferees
Ponnathapura Achutamurthy
SPE, Art Unit 1652

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Michael Wityshyn
SPE, Art Unit 1651

Michael G. Wityshyn (CONFEREE)
Supervisory Patent Examiner
Technology Center 1600

LEXICON GENETICS INCORPORATED
8800 TECHNOLOGY FOREST PLACE
THE WOODLANDS, TX 77381-1160